UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,625	04/02/2001	Albert S. Lee	22727-66	8907

21125 7590 11/26/2003

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	18

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/824,625	Applicant(s) LEE ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15 and 17-49* is/are pending in the application.

4a) Of the above claim(s) *20-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,15,17-19 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 7, 8 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine ('735).

Lafontaine provides a device for thermally treating tissue which includes an implantable member (14) having an outer surface for contacting target tissue. A fluid-tight lumen provides a cooled fluid to the implantable member and there are temperature sensors (22,24) located on the outer surface of the implantable member and on the surface of the delivery tube. The recitation of claims 7 and 8 is directed

towards the intended use of the device and bears little patentable weight to the claims. While Lafontaine does not specifically teach that the device is used to treat brain tissue, the examiner maintains that it is capable of such a use.

Claims 1-3, 5, 7, 8, 11, 12, 46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Milder ('215).

Milder provides a device which includes an implantable member (12) having an outer surface for contacting tissue. A fluid tight lumen (14) is defined by the implantable member and is configured to receive a thermally transmissive fluid. Milder provides first and second temperature sensors (122) for sensing tissue temperature as well as the temperature of the fluid within the tube (see Figure 14). Milder et al also provide a backing member (i.e. catheter supporting the implantable member).

Claims 1-5, 7-10, 19, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Wittenberger et al ('518).

Wittenberger et al provide a thermal treatment device which includes an implantable member (26) and a fluid tight lumen for delivering a thermally transmissive fluid to the implantable member such that the outer surface of the implantable member may be brought into contact with and treat targeted tissue. Again, the examiner maintains that the Wittenberger et al device is adapted for use in treating brain tissue. The Wittenberger et al implantable member may have various shapes including one looped around itself to form a coiled shape (Figure 9), and Wittenberger et al disclose

the use of one or more temperature sensors (20) as disclosed at column 3, line 15. Also, Wittenberger et al disclose the use of a backing material (25) attached to the implantable member (26). Finally, the implantable member may be made from a shape-memory material as disclosed at column 8, lines 27-30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine ('735) in view of the teaching of Burton et al ('271).

Lafontaine fails to specifically teach that the implantable member (i.e. balloon) is made from a silicone elastomer. The examiner maintains that one of ordinary skill in the art would recognize the well-known use of silicone elastomers in making surgical devices. In particular, Burton et al disclose another temperature treatment device which includes a balloon temperature transfer member just as in Lafontaine. Burton et al specifically teach that the balloon may be made from biocompatible materials such as silicone elastomers (col. 10, lines 14-19).

To have formed the Lafontaine balloon of any well known material which is biocompatible and yields acceptable heat transfer properties, such as silicone elastomers, would have been an obvious design consideration for one of ordinary skill in the art in view of the teaching of Burton et al.

Claims 12 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine ('735) in view of the teaching of Milder ('215).

Lafontaine provide a device which includes an implantable member filled with a thermally transmissive fluid and a first temperature sensor on the surface of the implantable member for measuring tissue temperature. While Lafontaine provides a second temperature sensor on the surface of the delivery tube, there is no specific teaching that the second temperature sensor should be located within the tube to detect the temperature of the fluid being delivered to the implantable member.

Milder provides substantially the same device which includes an implantable member (12) in communication with a fluid tight lumen which delivers a thermally transmissive fluid to the implantable member. In particular, Milder teaches of providing the device with a temperature sensor (122) for sensing tissue temperature and a second sensor (122) located within the tube for sensing the temperature of the fluid (Figure 14).

To have provided the Lafontaine system with a second sensor located within the delivery tube for monitoring the temperature of the delivered fluid would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Milder.

Claims15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine ('735) in view of the teaching of Goble et al ('134).

Lafontaine provides a thermally transmissive balloon apparatus, but fails to specifically teach of a pressure measurement element which monitors the pressure applied to tissue.

Goble et al also disclose a thermally transmissive balloon apparatus for applying pressure and thermal energy to tissue just as in Lafontaine. In particular, Goble et al also teach that it is advantageous to provide a pressure sensing element (see Abstract) to monitor the applied pressure to ensure it is within acceptable limits.

To have provided the Lafontaine balloon apparatus with a pressure measurement element to ensure the pressure of the balloon does not exceed acceptable limits would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Goble et al.

Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittenberger et al ('518) in view of the teaching of Burton et al ('271).

Wittenberger et al fail to specifically disclose the use of silicone elastomers as the material for making the implantable member. As addressed previously, it is the examiner's position that one of ordinary skill in the art would recognize the well-known use of silicone elastomers for making such medical devices.

In particular, Burton et al disclose another temperature treatment device which includes an implantable temperature transfer member. Burton et al specifically teach of the use of biocompatible materials such as silicone elastomers (col. 10, lines 14-19).

To have formed the Wittenberger et al implantable device of any well known material which is biocompatible and yields acceptable heat transfer properties, such as silicone elastomers, would have been an obvious design consideration for one of ordinary skill in the art in view of the teaching of Burton et al.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wittenberger et al ('518) in view of the teaching of Lafontaine ('735).

Wittenberger et al disclose the use of one or more temperature sensors located on the implantable member, but fails to specifically teach of the sensors located on a backing member.

Lafontaine teaches an analogous device and specifically teaches that temperature sensors may be located at various locations on the device, including on the heat transfer member (i.e. balloon) and on the support member attached to the balloon (see Figure 1, elements 22 and 24).

To have provided the Wittenberger et al device with multiple temperature sensors located at various locations, including the backing material, to obtain more complete temperature monitoring data would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Lafontaine.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lalonde et al ('959), Avitall ('280) and Jayaraman ('299) all disclose cryogenic devices which include an implantable member for treating tissue and temperature monitoring means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 19, 2003